REMARKS

Claims 1, 2, 4-13, 15-29, 36, 40-42, and 47-52 are pending. New claims 53 and 54 are respectively directed to an isolated nucleic acid molecule that encodes an acquired resistance polypeptide including an amino acid sequence that has at least 80% identity to the amino acid sequence of Fig. 5 (SEQ ID NO: 3) or Fig. 7B (SEQ ID NO: 14). Support for these claims is found, for example, on pages 8 (lines 5-7) and page 10 (lines 13-16). Entry of the amendments is believed to be appropriate and is respectfully requested.

Claim Rejections – 35 U.S.C. § 101

Claims 36 and 49 stand rejected under 35 U.S.C. § 101 as being unpatentable because the claimed invention is not supported by either a substantial asserted utility or a well-established utility. This rejection is traversed.

The analysis to be carried out in making a rejection under 35 U.S.C. § 101 must include a determination of whether an assertion of utility has been made in an Applicants' specification and, if so, whether that asserted utility is credible (*i.e.*, whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided; M.P.E.P. § 2107.02-III(B)).

In the present case, Applicants, as recognized by the Office, have asserted that the proteins are useful for antibody production and to monitor the level of the protein in a plant. Applicants submit that, absent data to the contrary, it is credible that using an anti-

NPR antibody will identify expression patterns of plants, for example, that are susceptible to pathogenic infection. Nonetheless, while the Office has stated that such a utility is not credible, no evidence has been provided that may be relied upon to reach this conclusion, as the Guidelines require. In particular, the Guidelines state that the Office

> must treat as true any statement of fact made by the Applicant in relation to the asserted utility, unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement... [I]t is improper to disregard the opinion [of a qualified expert] solely because of a disagreement over the significance or meaning of the facts offered. (M.P.E.P. § 2107 (D), emphasis added)

To be properly rejected under § 101, the Guidelines set forth that a case must represent one of those rare instances that meets the stringent criterion of being "totally incapable of achieving a useful result," *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555 (Fed. Cir. 1992), as cited in the Legal Analysis accompanying the Utility Examination Guidelines (M.P.E.P. § 2107.01-II). The only instances in which the federal courts have found a lack of patentable utility were where, "based upon the factual record of the case, it was clear that the invention could and did not work as the inventor claimed it did" (M.P.E.P. § 2107.01-II, emphasis added). These rare cases have been ones in which the applicant either (a) failed to disclose any utility for the invention, or (b) asserted a utility that could be true only "if it violated scientific principle, such as the second law of thermodynamics, or a law of nature, or was wholly inconsistent with contemporary knowledge in the art" (M.P.E.P. § 2107.02-IIIB).

Procedurally, the M.P.E.P. makes clear that the burden is on the Office to provide a detailed, reasoned explanation for the rejection that is supported, if possible, by documentary evidence indicating why the asserted utility is more likely than not "incredible." "An applicant's assertion of utility creates a presumption of utility" (M.P.E.P. § 2107.02-III(A)); "Where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being 'wrong,' even when there may be reason to believe that the assertion is not entirely accurate" (M.P.E.P. § 2107.02-III(B)). Conversely, if the Office determines that the claimed invention has a credible utility, neither a 35 U.S.C. § 101 nor a related 35 U.S.C. § 112 rejection may be applied (or, upon rebuttal of the Office's position, both rejections must be simultaneously reversed).

In the present case, Applicants' asserted utility in their specification, are, on their face, credible. Applicants assert that the present invention provides protein that can be used directly to generate diagnostic anti-NPR antibodies whereas, prior to the present invention, this was not possible because NPR was unavailable and its function was not known. Additionally, one skilled in the art would appreciate that NPR's ability to bind additional proteins enables NPR to be used for the isolation or purification of such NPR-binding proteins. No evidence has been made of record to dispute any of these utilities, and this rejection should be withdrawn.

Claim Rejections – 35 U.S.C. § 112, first paragraph

Claims 36 and 49 were rejected under 35 U.S.C. § 112, first paragraph. In particular, the Office asserts that, because the claimed invention is not supported by either a substantial asserted utility or a well established utility under § 101, one skilled in the art would not know how to use the claimed invention. For the reasons explained above, the related rejection under § 112, first paragraph should be withdrawn.

Claims 47-52 were rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. This rejection is traversed. Support for the language found in claims 47-52 is found in the specification, for example, at pages 41-44.

Claims 1-2, 4-13, 15-29, 36, 40-42, and 47-52 were rejected under 35 U.S.C. § 112, first paragraph as containing subject matter that was not described in the specification. This rejection is traversed.

Applicants assert that one skilled in the art would appreciate that an essential feature of the claimed invention is the ability of the claimed nucleic acid molecules to encode proteins that confer disease resistance on a plant. Applicants note that all of the pending claims, through the definition of acquired resistance polypeptide therefore include the functional limitation that the expressed protein confers disease resistance. Applicants further note that the assays described in the specification can readily be used by one skilled in the art to determine whether a protein confers disease resistance on a

plant.

In response to the Office's assertion that a functional limitation cannot be used to limit the claims because the "structural description "encoding a protein comprising an ankyrin repeat: is not sufficient," Applicants respectfully assert that further characterization of the claimed molecules is not necessary to distinguish the claimed proteins from other proteins. As stated in the Written Description Guidelines (66 FR 1106),

> [f]actors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient.

As noted above, the claimed proteins are distinguished from other proteins by both the structural characteristic of hybridizing to any one of the disclosed nucleic acid molecules and by the specific functional characteristic of conferring disease resistance on a plant that expresses such a nucleic acid. Based on Applicants' disclosure of these properties and routine assays for determining whether a particular protein has these properties, one skilled in the art would appreciate that Applicants were in possession of the claimed invention. Furthermore, there is no question that the claimed nucleic acid molecules (new

claims 53 and 54) that encode an acquired resistance polypeptide including an amino acid sequence that has at least 80% identity to the amino acid sequence of Fig. 5 (SEQ ID NO: 3) or Fig. 7B (SEQ ID NO: 14) are distinguished from other proteins by both the structural characteristic of having at least 80% sequence identity to SEQ ID NO:3 or 14 and by the specific functional characteristic of conferring disease resistance.

As clear distinguishing characteristics that are shared by the claimed nucleic acid molecules are disclosed in Applicants' specification, this basis of the rejection should be withdrawn.

Claims 1-2, 4-13, 15-29, 36, 40-42, and 47-52 remain rejected under 35 U.S.C. § 112, first paragraph as lacking enablement. For the following reasons, this rejection should be withdrawn.

The standard for enablement is articulated in *In re Wands* 858 F.2d 731, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988). In defining the boundaries of undue experimentation, the *Wands* court stated that "the key word is 'undue' not 'experimentation'" and that "the test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine." *Id.* at 737. As is discussed below, Applicants' specification meets this standard.

Like the practitioners of the monoclonal antibody art described in *Wands*, who screened many hybridomas to isolate the one having the desired characteristics, practitioners in the art of molecular biology are prepared to screen many molecules to find

one that contains a desired property. Such screening of molecules falling within Applicants' claims is considered to be a routine step in the process of isolating molecules having the desired characteristics; it cannot constitute undue experimentation.

As the case of *In re Wands* (858 F.2d 731, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988)) makes clear, enablement is not negated by the necessity for some experimentation such as routine screening. The present invention, like *In re Wands*, may involve screening. As stated *In re Wands*, "a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." In light of the teaching of the specification, screening nucleic acids for disease resistance or having the required percent identity falling within Applicants' claims might be laborious, but it would not require undue experimentation.

Addressing the Wands factors individually, Applicants note the following.

The Breadth of the Claims

Applicants note that, based on the disclosed sequences, it would not require undue experimentation for those of skill in the art to identify sequences from other plant species falling within the scope of Applicants' claimed invention. Indeed, determination of the sequence of a nucleic acid molecule and comparing the sequence to a reference sequence in recent years has even become a process that can be automated. Applicants thus submit that the present claims are not overly broad with respect to the disclosure provided in the

application.

Applicants further note that new claims 53 and 54 each require that the isolated nucleic acid molecule that encodes an acquired resistance polypeptide include an amino acid sequence that has at least 80% identity to the amino acid sequence of Fig. 5 (SEQ ID NO: 3) or Fig. 7B (SEQ ID NO: 14). Certainly, the application enables the scope of these claims: the sequences of the Arabidopsis NPR gene and protein sequences are provided in the application, and standard methods can be used to determine the sequence of a gene from virtually any other plant and be used to compare the sequence to any one of the sequences disclosed in the application (or a naturally occurring, allelic variant thereof). Undue experimentation certainly would not be required for carrying out such methods.

The Nature of the Invention and the State of the Prior Art

Applicants note that, as discussed above, based on Applicants' discovery of the Arabidopsis NPR genes and proteins, those of skill in the art could readily obtain the corresponding gene and protein from plants other than Arabidopsis. The state of the art in molecular biology is quite advanced, and undue experimentation would not be required to obtain such sequences from other plants. Nonetheless, as the sequence of the Arabidopsis genes are provided, this rejection should certainly not apply to new claims 53 and 54, which are specific for nucleic acid molecules that encode an acquired resistance polypeptide that include an amino acid sequence that has at least 80% identity to the amino acid sequence of Fig. 5 (SEQ ID NO: 3) or Fig. 7B (SEQ ID NO: 14).

The Amount of Direction or Guidance Presented and the Existence of Working Examples

Applicants respectfully submit that, based on the present inventors' discovery, it would be standard for those of skill in the art to determine the sequence of NPR genes from plants other than Arabidopsis. With respect to such plants, Applicants note that the Arabidopsis sequences are provided in the application, and it certainly would be standard to compare the sequence in the application (or a naturally occurring, allelic variant thereof) to the sequence of other plant genes to see if the test sequence includes, for example, an ankyrin repeat. It was also standard to test plants expressing such genes for disease resistance, which is known due to Applicants' discovery of the role of such proteins in disease resistance. Further, it is not necessary for Applicants to provide details as to how to carry out sequencing and sequence comparisons, as such methods were standard in the art. Applicants thus request that this rejection be withdrawn.

The Relative Skill of Those in the Art, the Predictability or Unpredictability of the Art, and the Quantity of Experimentation Necessary

The Examiner concludes that it would require undue experimentation to screen for genes that fall within the scope of Applicants' claimed invention.

Applicants respectfully disagree. As discussed above, isolation of genes from different organisms is standard, particularly if a sequence of a corresponding gene from one or more other organisms is available, as in the present case. Also as discussed above,

sequencing and sequence comparison are standard methods and, indeed, can be automated. If a gene is found it is then readily tested for the ability to confer disease resistance using routine testing.

Applicants also note that the relative skill of those in this art is high and, as is discussed above, undue experimentation certainly would not be required to identify and sequence genes from different organisms. This basis for the rejection under § 112, first paragraph should therefore be withdrawn.

Claim Rejections – 35 U.S.C. § 112, second paragraph

Claims 10-13, 15-29, 36, 40-42, and 47-52 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. For the following reasons, these rejections should be withdrawn.

Claims 10-12, 17, 22, 36, and 40 were deemed indefinite in their recitation of the term "hybridizes." In particular, the Office notes that "examples do not define a term, and other definitions are possible." This rejection is traversed.

Applicants first point out that the phrase "hybridizes" should not be taken out of context. Next, like the claims, Applicants' specification, for example, at page 12 (lines 1-3), page 49 (lines 14-20), and pages 51 (line 12) - 52 (line 3), makes the meaning of this claim term clear and definite. Given this description, one skilled in the art would readily understand the meaning of the term "hybridizes," and as such, this description

"reasonably apprises those skilled in the art" of the scope of the present claims. See, for example, *Miles Laboratories, Inc. v. Shandon, Inc.*, 997 F.2d 870, 27 U.S.P.Q.2d 1123 (Fed. Cir. 1993) ("If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more...The degree of precision necessary for adequate claims is a function of the nature of the subject matter."). Reconsideration on this point is requested.

Claim 28 was deemed unclear if the seed comprises the nucleic acid or vector. This rejection has been met by the present rejection.

Claim 50 was deemed indefinite for being dependent upon a cancelled claim. This rejection has been met by the present amendment.

Claim Rejections – 35 U.S.C. § 102

Claims 1-2, 4-13, 15-29, 36, 40-42, and 47-52 remain rejected under 35 U.S.C. § 102(e) as being anticipated by Ryals et al (US Patent 6,091,004, filed June 1996). As Applicants have addressed herein all of the outstanding issues in this case, an interference can now be declared. Further, for a second, independent reason, if at least one of the pending claims in this application is found allowable and is claiming the same invention as at least one claim of the Ryals '004 patent, Applicants respectfully request that the Office proceed to propose an interference.

Claims 1-2, 4, 6-13, 15-25, 28-29, 36, and 40-42 were rejected under 35 U.S.C. § 102(b) as being anticipated by Zhang et al. Zhang is cited for teaching a protein with 4

ankyrin repeats. Because Zhang fails to disclose a polypeptide capable of triggering a plant acquired resistance response (for example, a systemic acquired resistance (SAR) or local acquired resistance response (LAR)) in a plant cell or plant tissue, this rejection should be withdrawn.

Double Patenting

Claims 1-2, 4-13, 15-29, 36, 40-42, and 47-52 remain provisionally rejected under the judicially created doctrine of double patenting over claims 1-25 of copending application no. 09/908,323. As noted previously, Applicants agree to address this rejection, of appropriate, upon an indication of allowable subject matter.

CONCLUSION

Applicants submit that this case is now in condition for allowance, and such action is respectfully requested.

Enclosed is a Petition to extend the period for replying to the Office Action for three months, to and including February 28, 2005, and a check $510.00 in payment of the required extension fee.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 28 February 2005

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